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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
PAT051386-US-CIP01	
Application Number: 09/610,313	Filed: July 5, 2000
First Named Inventor: Susan W. BARNETT et al.	
Art Unit: 1635	Examiner: J. Angell

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [ ] attorney or agent of record. Registration number _____
- [x] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. 48,751

/Otis Littlefield/
Signature

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Typed or printed name

(415) 268-6846
Telephone number

January 12, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

Novartis Reference: PAT051386-US-CIP01
Mofo Reference: 223002109720

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Susan W. BARNETT et al.

Application No.: 09/610,313 Confirmation No.: 4221

Filed: July 5, 2000 Art Unit: 1635

For: POLYNUCLEOTIDES ENCODING ANTIGENIC HIV TYPE C POLYPEPTIDES, POLYPETIDES AND USES THEREOF Examiner: J. Angell

ARGUMENTS ACCOMPANYING PRE-APPEAL BRIEF REQUEST FOR REVIEW

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

The following arguments are presented in support of the Pre-appeal Brief Request for Review being filed concurrently with a Notice of Appeal.

ARGUMENTS

1. Claim Rejections 35 U.S.C. § 112

The Examiner has maintained the rejection of Claims 1-40, 43-47, 52, and 53 under 35 U.S.C. § 112, first paragraph, alleging that amended Claim 1, which no longer recite "an HIV Pol polypeptide" (Office Action), does not meet the written description requirement due to lack of a "disclosed correlation between function and structure".

Applicants respectfully traverse the rejection and its supporting remarks. Claim 1 currently recites:

> An expression cassette, comprising a polynucleotide sequence operably linked to a promoter, wherein the polynucleotide sequence has at least 90% sequence identity to the polynucleotide sequence presented in Figure 8 (SEQ ID NO:30); Figure 9 (SEQ ID NO:31); or Figure 10 (SEQ ID NO:32).

The Examiner's interpretation of the written description requirement is inconsistent with the USPTO's latest Written Description Guidelines. The USPTO Written Description Training Materials, Revision 1, March 25, 2008, states in Example 11A, Art-Recognized Structure-Function Correlation Not Present, page 37, Analysis Claim 1:

> Claim 1:
> "An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2."
> Analysis Claim 1:
> "There is no functional limitation on the nucleic acids of claim 1 other than that they encode the polypeptide of SEQ ID NO: 2 or any polypeptide having 85% structural identity to SEQ ID NO: 2. The genetic code and its redundancies were known in the art before the application was filed. The disclosure of SEQ ID NO: 2 combined with the pre-existing knowledge in the art regarding the genetic code and its redundancies would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2. With the aid of a computer, one of skill in the art could have identified all of the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2. Thus, one of ordinary skill in the art would conclude that the applicant was in possession of the claimed genus at the time the application was filed.

> Conclusion: The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the scope of claim 1."

There is no meaningful distinction between pending claim 1 and claim 1 of Example 11A of the USPTO's current Written Description Guidelines. In view of that, the Examiner's statement that "the instant claims encompass a genus of molecules that are structurally related, but which may be functionally unrelated" and that "as such, the required correlation between function and structure for the claimed genus of molecules has not been provided", is incorrect in view of the latest Written Description Training Materials and the fact that, as currently pending, claim 1 does not recite a function. Thus the applicants have satisfied the current written description requirements as set forth in the latest Written Description Training Materials. Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 1-40, 43-47, 52, and 53 under 35 U.S.C. § 112, first paragraph.

2. Double Patenting 35 U.S.C. § 101

The Examiner has maintained the statutory type double patenting rejection of Claims 1, 5-11, and 19-21 under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 1, 16-22, and 30-32 of U.S. Patent No. 7,211,659 (Application No. 10/190,135).

Applicants respectfully traverse the rejection and its supporting remarks. The Examiner asserts that instant currently pending "claim 1 encompasses any polynucleotide sequence that has within it a sequence that is at least 90% identical to SEQ ID NO: 30, 31 or 32. Thus, SEQ ID NO: 9 of the issued patent does 'have' at least 90% sequence identity to the polynucleotide sequences of SEQ ID NO: 30, 31 or 32, and thus the rejection is proper."

However, the MPEP states (A. Statutory Double Patenting — 35 U.S.C. 101; MPEP 800-19):

> "A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope

of one claim, but not the other? ***If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist***." (emphasis added)

Thus, if there is an embodiment of the invention that is within the scope of pending claim 1, but not within the scope of issued claim 1 of U.S. Patent No. 7,211,659, then there is no statutory double patenting. Issued claim 1 of U.S. Patent No. 7,211,659 reads:

> 1. An expression cassette, comprising a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Gag polypeptide, wherein the polynucleotide sequence encoding said immunogenic HIV Gag polypeptide comprises a sequence having at least 90% sequence identity to SEQ ID NO:9.

SEQ ID NO:9 in U.S. Patent No. 7,211,659 is 3930 nucleotides in length. By contrast, SEQ ID NO: 30 of the present application is 2469 nucleotides in length. Thus, the appropriate expression vector in accordance with pending claim 1 comprising SEQ ID NO:30 is within the scope of pending claim 1, but is not within the scope of issued claim 1 of U.S. Patent No. 7,211,659 since is it a mathematical impossibility for a nucleotide sequence which is 2469 nucleotides in length (as SEQ ID NO: 30) to be 90% identical to a sequence of 3930 nucleotides as required by claim 1 of U.S. Patent No. 7,211, 659 (2469/3930 x 100% = 62.8%).

Consequently, the test for statutory double patenting test as set forth in the MPE is not met given that there is an embodiment that is covered by the currently pending claim but not by the issued claim 1 of U.S. Patent No. 7,211, 659. Applicants therefore respectfully request that the Examiner withdraw the statutory type double patenting rejection of Claims 1, 5-11, and 19-21 under 35 U.S.C. § 101.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002109720. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 12, 2010

Respectfully submitted,

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